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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,791	12/22/1998	KOUJI MATSUSHIMA	350292000500	3409

25225 7590 01/29/2004

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/202,791

Applicant(s)

MATSUSHIMA ET AL.

Examiner

Deborah K. Ware

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 22 December 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Attachment A.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 16-29 and 31-44.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): 35 USC 112, second paragraph in part only for claims 19-22 and 34-37.

## **ATTACHMENT A**

Claims 16-29 and 31-44 are presented for reconsideration on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed December 22, 2003 has been received and will be entered.

The rejection under 35 USC 112, second paragraph will be removed for claims 19-22 and 34-37. However, the rejection is maintained for the other rejected claims 16-18, 23-29, 31-33 and 38-44 because of the reasons of record, note prior final office action of June 18, 2003, see page 2. With respect to claims 19-22 and 34-37 a person of ordinary skill in the art would be able to understand the scope because it is defined in the claims, as it should be. However, the argument that "other indirect causes" would be understood as well is not deemed persuasive since the specification does not support any other causes per se. The metes and bounds of the claims can not be clearly delineated as argued by Applicants when no "other indirect causes" associated with hypoxemia are exemplified in the instantly filed specification, especially when their mechanism of onset greatly differ from one another.

The rejection of claims 16-29 and 31-44 under 35 USC 103 over Folkesson et al. in view of Slotman is maintained. However, Applicants' arguments have been considered along with the reference copies of descriptions from Review of Medical Physiology, specifically pages 594-595 and pages 636-648. Applicants set forth that none of these descriptions mention hypoxemia and therefore, the cited prior art

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combination of record is alleged by Applicants to not teach or suggest the claimed methods of treating hypoxemia in acute lung injury. However, Slotman clearly teaches that the acute lung injury, adult respiratory distress syndrome (ARDS), is manifested clinically by hypoxemia, note col. 6, lines 16-17. Further, indirect causes occur systemically and Slotman clearly teaches that it is believed that systemic inflammatory conditions such as ARDS, are the result of a severe generalized autodestructive inflammation and further that ARDS is manifested by hypoxemia. Note col. 6, lines 14-17 of Slotman. Clearly hypoxemia is associated with acute lung injury onset via indirect causes. The cited references applied clearly describe what the descriptions from Review of Medical Physiology are lacking as set forth by Applicants. Therefore, Applicants' arguments are not deemed persuasive.

Also the argument that Folkesson was limited only to lung injury caused by acid inhalation is noted, however, Folkesson clearly teach acid aspiration lung injury of which they hypothesize that a major acid induced cytokine was IL-8 (interleukin-8) and that a neutralizing anti-IL-8 antibody would attenuate acid induced lung injury. Note the abstract, lines 1 and 3-5. The acid-instilled mammalian test subjects given anti-IL-8 antibody as treatment attained protected lung function and experienced improved lung function in response to anti-IL-8 antibody treatment (see abstract, lines 12-20). The argument that direct cause is taught by Folkesson et al. is noted, however, Slotman clearly teaches indirect causes and direct as well as indirect causes would have been expected to be treatable using the anti-IL-8 antibody treatment. Therefore, no unexpected successful result has been obtained by Applicants' claimed methods.

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Slotman clearly teaches indirect causes of acute lung injury such as those caused by systemic inflammatory conditions.

Slotman also teaches method for identifying and monitoring patients at risk for these conditions of which includes measuring concentrations of acute inflammatory response mediators of which includes IL-8. Note col. 25, lines 1-10 and lines 49-58. Folkesson et al clearly teach that anti-IL-8 antibody is an useful treatment for lung injury. Therefore, the combination of the cited references clearly suggests treating hypoxemia using anti-IL-8 antibody. To combine anti-IL-8 antibody with a carrier such as water or saline solution is clearly an obvious modification of the cited prior art. One of skill would have been motivated to combine anti-IL-8 antibody with a carrier in order to treat hypoxemia manifested by ARDS resulting from a systemic inflammatory condition or indirect cause. Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The claims remain *prima facie* obvious over the combination of cited prior art of record.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.



Deborah K. Ware  
January 20, 2004



DAVID M. NAFF  
PRIMARY EXAMINER  
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